

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOHN STARKS : CIVIL ACTION
 :
 v. :
 :
 COLOPLAST CORPORATION : No. 13-3872

MEMORANDUM

McLaughlin, J.

February 13, 2014

This action arises from the malfunction of the plaintiff's penile inflatable implant,¹ a Titan OTR Inflatable Penile Implant ("Titan implant"), which is manufactured by the defendant. The plaintiff, John Starks, sued the defendant, Coloplast Corp., for negligence, strict products liability, breach of warranties, and breach of contract. The Court considers here a motion to dismiss by Coloplast pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, the Court will grant Coloplast's motion, dismiss the negligence, strict liability, and breach of implied warranty claims with prejudice, and dismiss the breach of express warranty and breach of contract claims without prejudice.

¹ A "penile inflatable implant" is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. Such devices are used in the treatment of erectile impotence. 21 C.F.R. § 876.3350(a).

I. Background²

A. Premarket Approval of the Titan Implant

The Court relies on the publicly available U.S. Food and Drug Administration ("FDA") documents attached to Coloplast's motion to dismiss on the issue of the premarket approval of the Titan implant.³

The Titan implant, which was originally called the Mentor Alpha I Inflatable Penile Prosthesis, received premarket approval from the FDA on July 14, 2000. The original premarket

² The Court accepts all well-pleaded facts in the complaint as true and draws all reasonable inferences in favor of the non-moving party, while disregarding any legal conclusions. See Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).

³ Matters of public record may be considered without converting a motion to dismiss into a motion for summary judgment. Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). On a motion to dismiss, courts take judicial notice of documents that are matters of public record such as Securities and Exchange Commission filings, court-filed documents, and FDA reports published on the FDA website. McGehean v. AF & L Ins. Co., No. 09-01792, 2009 WL 3172763, at *2 (E.D. Pa. Oct. 2, 2009) (citing In re Wellbutrin SR/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003)). The Court takes judicial notice of the documents attached to Coloplast's motion as public records of the FDA.

The Court does not consider the documents attached to Starks's opposition to the motion to dismiss, which include Starks's medical records. Consideration of such documents would convert this motion into one for summary judgment.

approval application for the implant was submitted by Mentor Corporation.⁴ Def.'s Mot., Ex. 1.

Since 2000, both Mentor and Coloplast have submitted several supplements to the original premarket approval, all of which have been approved by the FDA. On June 14, 2002, the FDA approved a supplemental premarket approval application that allowed the Titan implant to incorporate a hydrophilic coating. Def.'s Mot., Ex. 5. On January 14, 2003, the FDA approved another supplemental premarket approval application that allowed further hydrophilic coating of the implant and marketing of the device under a different name—the "Mentor Titan Inflatable Penile Prosthesis." Def.'s Mot., Ex. 6. Lastly, on June 13, 2008, the FDA approved a supplemental premarket approval application submitted by Coloplast that allowed several modifications to the device, as well as marketing of the device under the trade name "Titan OTR Inflatable Penile Prosthesis." Def.'s Mot., Ex. 7.

⁴ Coloplast asserts that Mentor is its predecessor-in-interest, and that Coloplast purchased the Titan implant in 2006. Def.'s Mot. at 7-8.

B. Starks's Titan Implant

Starks was admitted to Hahnemann University Hospital in Philadelphia on or about March 15, 2010. Starks's urologist, Bruce Garber, MD, surgically implanted the Titan implant into Starks's penis at that time. Compl. ¶ 3.

On or about January 25, 2012, Starks's Titan implant stopped working, leaked, and "otherwise would not operate." Id. ¶ 6. Dr. Garber reported that the Coloplast penile implant "malfunctioned due to a fluid leak." Id. ¶ 7.

Starks underwent another surgery on March 20, 2012, at Lankenau Medical Center to remove the Titan implant and have another penile device implanted. Id. ¶ 8. Surgeon Max Ahn, MD, examined the implant and described the malfunction as a result of "a break in the tubing of the right corporal cylinder." Id. ¶ 9.

As a result of the malfunction in his Titan implant, Starks was forced to undergo additional surgery to remove the implant and have a new one implanted and is now subject to the related medical bills. He also suffered from post-surgical pain, additional scar tissue, other pain and suffering, loss of the pleasures of life, including his sexual life, embarrassment and humiliation, and impairments of his bodily functions. Id. ¶ 10.

C. Procedural History

Starks initially filed this action in the Court of Common Pleas of Philadelphia County on May 31, 2013. Coloplast was served with the complaint on June 4, 2013, and Coloplast timely removed the case to the Eastern District of Pennsylvania on July 2, 2013.

Coloplast filed its motion to dismiss on July 23, 2013, and briefing on that motion was completed with Coloplast's reply brief, filed on August 13, 2013.

II. Legal Standard

A motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the sufficiency of the complaint. Conley v. Gibson, 355 U.S. 41, 45 (1957), abrogated in other respects by Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007). A claim may be dismissed under Rule 12(b)(6) for "failure to state a claim upon which relief can be granted."

Generally, in ruling on a motion to dismiss, the court relies on the complaint, attached exhibits, and matters of public record. Pension Benefit Guar. Corp., 998 F.2d at 196. FDA reports published on the FDA website are public records that the court may judicially notice. McGehean, 2009 WL 3172763, at *2.

Although Rule 8 of the Federal Rules of Civil Procedure requires only that the complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief" to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests," the plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555 (quoting Fed. R. Civ. P. 8(a)(2) and Conley, 355 U.S. at 47). Similarly, naked assertions devoid of further factual enhancement will not suffice. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Twombly, 550 U.S. at 557).

Although "conclusory" or "bare-bones" allegations will not survive a motion to dismiss, Fowler, 578 F.3d at 210, a complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008).

The court is required to conduct a two-part analysis when considering a Rule 12(b)(6) motion. First, the factual matters averred in the complaint, and any attached exhibits, should be separated from legal conclusions asserted. Fowler, 578 F.3d at 210. Any facts pleaded must be taken as true, and

any legal conclusions asserted may be disregarded. Id. at 210-11. Second, the court must determine whether those factual matters averred are sufficient to show that the plaintiff has a "plausible claim for relief." Id. at 211 (quoting Iqbal, 556 U.S. at 679).

This two-part analysis is "context-specific" and requires the court to draw on "its judicial experience and common sense" to determine if the facts pleaded in the complaint have "nudged [plaintiff's] claims" over the line from "conceivable to plausible." Iqbal, 556 U.S. at 679-80. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 678.

The Third Circuit has summarized the post-Twombly standard as follows: "[S]tating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." Phillips, 515 F.3d at 234 (alteration in original) (citations omitted) (quoting Twombly, 550 U.S. at 556).

III. Discussion

A. Negligence, Strict Liability, Breach of Warranty, and Preemption Under the Medical Device Amendments

1. The Medical Device Amendments

The Titan implant is a Class III medical device approved by the FDA.⁵ The FDA separates medical devices into three categories, depending on their level of risk. Class III devices include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. They receive the most oversight from the FDA. Williams v. Cyberonics, Inc., 654 F. Supp. 2d 301, 304 (E.D. Pa. 2009) (citing Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008)), aff'd, 388 F. App'x 169 (2010).

The Medical Device Amendments of 1976, 21 U.S.C. §§ 360c et seq. ("Medical Device Amendments"), require new Class III devices to undergo a rigorous process known as premarket approval.⁶ Premarket approval includes an in-depth review of

⁵ FDA regulations classify penile inflatable implants as Class III medical devices. 21 C.F.R. § 876.3350(b).

⁶ On April 12, 2000, the FDA promulgated a regulation requiring all "penile inflatable implants" to "have an approved [premarket approval] or a declared completed [product development protocol] in effect" in order to be placed in commercial distribution. 21 C.F.R. § 876.3350(c); see also

scientific and clinical data. The FDA spends an average of 1,200 hours reviewing each application. Williams, 654 F. Supp. 2d at 304 (citing Riegel, 552 U.S. at 317-18). The FDA is required to weigh "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). The FDA may approve devices that pose significant risks to the patient if they also offer large benefits. Williams, 654 F. Supp. 2d at 304 (citing Riegel, 552 U.S. at 318). After a device has been approved, the manufacturer cannot change design specifications that affect safety or effectiveness without FDA permission. Id.

2. Preemptive Effect of the Medical Device Amendments

The Medical Device Amendments expressly preempt certain state law requirements, stating that:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

Gastroenterology – Urology Devices; Effective Date of Requirement for Premarket Approval of the Penile Inflatable Implant, 65 Fed. Reg. 19,658 (Apr. 12, 2000) (codified at 21 C.F.R. pt. 876).

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court addressed the Medical Device Amendments' preemption clause in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), a case involving a Class III catheter approved by the FDA through the premarket approval process. The Supreme Court held that Riegel's strict liability claim, breach of implied warranty claim, and all of his negligence claims, except for a negligent manufacturing claim, were preempted by the premarket approval of the catheter by the FDA. Id. at 324-25.

The Supreme Court established a two-part test for determining whether a claim is preempted. First, a court must determine whether the federal government has established requirements applicable to the medical device. Id. at 321-22. Second, a court must determine whether the state common law claims impose requirements that are "different from, or in addition to" those imposed by federal law. Id.⁷

⁷ Because state requirements are preempted only to the extent that they are "different from, or in addition to" the requirements imposed by federal law, the Medical Device Amendments do not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to,

3. Preemption of State Law Torts⁸

State common law claims against manufacturers of medical devices that are approved through premarket approval are subject to federal preemption. Riegel, 552 U.S. at 322-25. The Supreme Court determined that the Medical Device Amendments' express preemption clause "bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA]." Id. at 315. The Court concluded that

federal requirements. Riegel, 552 U.S. at 330 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996) (plurality opinion)).

⁸ Starks argued in his opposition to the motion to dismiss that his claims were not preempted because the Titan implant was approved via the "substantial equivalency" § 510(k) procedure in 1989, rather than via the premarket approval process. Pl.'s Opp. at 2. Approval under § 510(k) does not result in the same preemptive effect as does premarket approval. The "substantial equivalence" clearance under the § 510(k) notification process "does not impose any federal 'requirement' applicable to the device, but is rather a 'generic federal standard.'" Horn v. Thoratec Corp., 376 F.3d 163, 168 (3d Cir. 2004) (quoting Lohr, 518 U.S. at 486-87 (plurality opinion)). Riegel distinguished the § 510(k) clearance in stating that the premarket approval process contained device-specific requirements that § 510(k) clearance did not. Riegel, 552 U.S. at 322-23. The § 510(k) clearance of a medical device's predicate or its components, however, does not change the preemptive effect of premarket approval of the current device. See Smith v. Depuy Orthopaedics, Inc., No. 11-4139, 2013 WL 1108555, at *12 (D.N.J. Mar. 18, 2013); Gross v. Stryker Corp., 858 F. Supp. 2d 466, 488 (W.D. Pa. 2012); Bentzley v. Medtronic, Inc., 827 F. Supp. 2d 443, 451-52 (E.D. Pa. 2011). The Titan implant received premarket approval in 2000, and that premarket approval has preemptive effect.

claims for strict liability, breach of implied warranty, and negligence suggest that "a device was designed, labeled, or manufactured in an unsafe or ineffective manner." Id. at 328.

The Supreme Court also concluded that premarket approval devices are subject to "requirements" that are "specific to individual devices." Id. at 322-23. Premarket approval was characterized as "[a] federal safety review" in which "the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness." Id. at 323 (citing 21 U.S.C. § 360e(d)). Therefore, state law claims premised on tort duties regarding effectiveness are "requirements" that are preempted by the premarket approval process. Id. at 323-25.

Here, the FDA documents attached to the defendant's motion to dismiss illustrate that the Titan implant received premarket approval. Several supplemental premarket approval applications were also approved for the Titan implant. See Def.'s Mot., Exs. 1, 5-7. Therefore, the federal government has imposed device-specific "requirements" on the Titan implant, and the first prong of the two-part test of express preemption under § 360(k) has been fulfilled. See Riegel, 552 U.S. at 322-23.

The Court next determines whether Starks's claims based on negligence, strict liability, and breach of warranty

are expressly preempted by the Medical Device Amendments. The second prong of express preemption under § 360(k) requires this Court to evaluate whether the state requirements underlying Starks's claims relate to the device's safety and effectiveness and are "different from or in addition to" the federal requirements. Id. at 323.

a. Negligence

Starks's claims of negligence regarding the Titan implant are preempted. Riegel, 552 U.S. at 320, 325 ("[T]ort law, applied by juries under a negligence or strict-liability standard," such as state tort claims alleging "negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of [a Class III medical device]," is preempted by the Medical Device Amendments); see also Horn v. Thoratec Corp., 376 F.3d 163, 173 (3d Cir. 2004) ("[I]t is firmly established that a 'requirement' under § 360k(a) can include legal requirements that arise out of state common-law damages actions.").

Starks's complaint includes two paragraphs that allege a "fail[ure] to comply with state duties equal to, or substantially identical to, federal requirements" and a "fail[ure] to abide by and follow federal regulations such as identifying testing, inspections, adverse effects and other

clinical and nonclinical information demonstrating that the inflatable penile implant is safe." Compl. ¶ 12(1), (m). Starks's "broad references to federal regulations are insufficient to establish the duty element of a negligence state law claim which would parallel a violation of federal law." Gross, 858 F. Supp. 2d at 494.

b. Strict Liability

Starks's strict liability claims are also expressly preempted. Strict liability theories based on a device's alleged manufacturing and design defects are state requirements that are preempted by the Medical Device Amendments because of their potential conflict with FDA labeling, design, and manufacturing requirements. See Bentzley, 827 F. Supp. 2d at 453 (citing Riegel, 552 U.S. at 330); see also Williams, 388 F. App'x at 171-72.

Furthermore, Starks's strict liability allegations are even more general than his allegations of negligence and do not plead "a violation of FDA regulations." He alleged that Coloplast "manufactured, distributed, assembled . . . tested, inspected, sold and placed into the stream of commerce a penile implant which it defectively designed" and "which malfunctioned and was unreasonably dangerous." Compl. ¶¶ 16-17. Starks did

not assert that Coloplast has in any way failed to conform to the FDA requirements prescribed by its premarket approval or that Coloplast deviated from or violated any of the FDA's federal statutes or regulations. See Horn, 376 F.3d at 179.

c. Breach of Implied Warranty

Starks alleges one count regarding breach of warranties. See Compl. ¶¶ 22-27. There, Starks makes allegations regarding both express and implied warranties. The Court addresses here Starks's allegations regarding the implied warranties of merchantability and fitness for a particular purpose, while Starks's allegations regarding express warranties are addressed in the next section. Starks's allegations regarding implied warranties cite Pennsylvania statutes and include no discussion of any "violation of FDA regulations." See Compl. ¶¶ 23, 25-26.

Starks's implied warranty claims are preempted by the Medical Device Amendments. Pennsylvania has adopted the Uniform Commercial Code formulations of the implied warranties of merchantability and fitness for a particular purpose. 13 Pa. Cons. Stat. § 2314, 2315. An implied warranty claim is centered on the accepted standards of design and manufacture of products in the state of Pennsylvania. See Bentzley, 827 F. Supp. 2d at

454 (citing Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 434 (E.D. Pa. 2004)).

"The FDA, . . . in its regulations and premarket approval relating to" the Titan implant, "has provided federal requirements relating to the design and manufacture" of the Titan implant. Id. Because Starks's allegations relate to standards that are different from, or in addition to, the federal requirements, Starks's implied warranty claims are preempted by the Medical Device Amendments. See Riegel, 552 U.S. at 325, 330; Williams, 388 F. App'x at 171.

B. Breach of Express Warranty

Starks asserts a cause of action for breach of express warranty, alleging that "Defendant gave Plaintiff express warranties under 13 Pa.CSA § 2313, and assured Plaintiff that the penile implant was in good, working condition, and of good materials." Compl. ¶ 24. Starks makes several allegations regarding the substance of these warranties: the Titan implant "was advertised, marketed, represented and warranted by Defendant to be of superior quality, and to be reliable for five years"; the Titan implant was "dependable," "reliable," and "would provide satisfaction"; "the penile implant would work a

minimum of five years"; and "a failed or malfunctioning penile implant would be replaced for a lifetime." Id. ¶¶ 5, 27.

Attached to the complaint is a Coloplast brochure entitled "Straight Talk about Erectile Dysfunction Patient Guide," addressed to Dr. Garber. Compl., Ex. A. Circled in that brochure is the statement "Lifetime replacement policy: Coloplast provides a lifetime replacement policy with all of its penile implants. Coloplast will replace the inflatable implant, or any component, for any reason during the lifetime of the patient." Id. In Starks's complaint, he references this exhibit in his breach of contract count but not in his breach of warranties count. In Starks's opposition to the motion to dismiss, however, he does reference Coloplast's "promises and assurances in its own promotional and marketing materials." Pl.'s Opp. at 3.

A claim for breach of an express warranty is not preempted by the Medical Device Amendments. Express warranties do not independently arise by operation of state law, and the parties, not the state, define the obligations of the contract and therefore any express warranties. See Bentzley, 827 F. Supp. 2d at 454-55.

Under Pennsylvania law, an express warranty arises out of the representations or promises of the seller. 13 Pa. Cons.

Stat. § 2313. An express warranty is created by a seller through "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." Id. A promise becomes the basis of the bargain if the plaintiff can prove "that she read, heard, saw or knew of the advertisement containing the affirmation of fact or promise." Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 452 (W.D. Pa. 2004) (quoting Cipollone v. Liggett Grp., Inc., 893 F.2d 541, 567 (3d Cir. 1990), rev'd on other grounds, 505 U.S. 504 (1992)). Absent a demonstration that a promise or affirmative statement was made, how or by whom the promise was made, or what was in fact promised, a claim for breach of express warranty is not sufficiently plead. Gross, 858 F. Supp. 2d at 501-02.

Starks has failed to allege any affirmation of fact or promise made by Coloplast that relates to the Trident implant that would amount to an express warranty. Additionally, Starks has not plead any details regarding the content of any express warranty, how it was made, that it became the basis of the bargain, or that it was directed to Starks. Therefore, Starks has not set forth the elements of a breach of express warranty cause of action. Starks's failure to support his conclusory statements regarding breach of an express warranty with any

factual allegations does not meet the pleading standard set forth in Twombly. "Without any indication that an express warranty was made and without providing the content of any alleged warranty, it is impossible to find that an express warranty exists, let alone that a breach occurred." Gross, 858 F. Supp. 2d at 502; see also Delaney v. Stryker Orthopaedics, No. 08-03210, 2009 WL 564243, at *6 (D.N.J. Mar. 5, 2009). Therefore, Starks fails to state a claim for breach of express warranty.

The Court will dismiss this claim without prejudice and allow the plaintiff thirty days to file an amended complaint with regard to the breach of express warranty claim.

C. Breach of Contract

Pennsylvania law requires that a plaintiff seeking to proceed with a breach of contract action must establish "(1) the existence of a contract, including its essential terms, (2) a breach of a duty imposed by the contract[,], and (3) resultant damages." Ware v. Rodale Press, Inc., 322 F.3d 218, 225 (3d Cir. 2003).

Starks alleges that he received a Coloplast implant in 2010 and that "Plaintiff and Defendant had a bargained for contract in which Defendant promised to replace the penile

implant throughout Plaintiff's lifetime." Compl. ¶¶ 3, 29.

Exhibit A, cited by Starks as containing the contract between Coloplast and himself, appears to the Court to be an excerpt from an advertising brochure addressed to Dr. Garber.

The Court agrees with Coloplast that Starks does not adequately allege the elements of a cause of action for breach of contract. Rather, Starks "mis-labels snippets from an advertising brochure mailed to a third party." Def.'s Reply at 10. The "Straight Talk" document attached at Exhibit A does discuss a lifetime replacement policy, but it is not clear to the Court that the brochure sets forth the terms of any agreement between the parties. For example, the document is not signed or dated. Starks has also not alleged that there was any offer and acceptance between Coloplast and himself. Therefore, Starks fails to state a claim for breach of contract.

The Court will dismiss this claim without prejudice and allow the plaintiff thirty days to file an amended complaint with regard to the breach of contract claim.

IV. Conclusion

For the reasons stated above, the Court will grant the defendant's motion to dismiss. The plaintiff's negligence, strict liability, and breach of implied warranty claims are dismissed without prejudice. The plaintiff's breach of express warranty and breach of contract claims are dismissed with prejudice.

An appropriate Order shall issue.